

## **REMARKS**

### **Claim Status**

Claim 17 is cancelled.

Claims 1-16 and 18-20 are currently amended and are supported by the original application (e.g., Examples and original claims).

Claim 21 is new and recites subject matter from claim 16 as previously pending.

Applicants respectfully submit that the foregoing amendments to the claims do not introduce any new subject matter to the application. With the present amendments, there are twenty claims pending, namely claims 1-16 and 18-21.

### **Claim Objections**

Claim 10 is objected to for reciting “fur.” This typographical error is corrected in the current amendment by entering the preposition “for.”

### **Claim Rejections – 35 USC § 112, Second Paragraph**

Claims 1-16 and 18-20 are rejected under 35 USC § 112 as being indefinite. The Examiner lodges several different allegations that are discussed in the following remarks.

Claim 1 is alleged to be unclear for reciting “rapid” and “protein mixture.” These terms are not recited in claim 1 as currently amended. The phrases “unbound monoclonal antibody” and “bound stabilizer” are alleged to be unclear for lack of antecedent basis. Claim 1 is currently amended to recite washing or removing of monoclonal antibody and stabilizer that are unbound to the support after their respective application steps. Skilled artisans would understand that a fraction of any protein (e.g., antibody) or blocking agent applied to a support would not bind thereto, and therefore would be in the unbound state and readily removable.

The recitation “protein/antigen” in claim 2 is alleged to lack antecedent basis. Claim 2 as currently amended specifies that the molecule recognized by the first and second antibodies is a protein.

The recitations “used” and “preferably” are alleged to render claim 3 unclear. As currently amended, claim 3 does not recite these terms. The features that were previously the subject of the “preferably” clause are now directly recited in claim 7. The “drying” feature of claim 7 is removed, since lyophilization and freeze-drying refer to the same process, which is already recited in claim 1 (lyophilization).

The recitation “blocking agent” in claim 8 is alleged to lack antecedent basis. Claim 8 is currently amended to specify that the second and third antibodies are dissolved with a blocking agent, thereby introducing this term to the claim.

The recitation “material” in claim 10 is alleged to lack antecedent basis. This term is not recited in claim 10 as currently amended.

The recitations “second antibody” and “third antibody” in claims 12-14 are alleged to be unclear for reasons of antecedent basis. These terms are now recited as “the second antibody” and “the third antibody” to indicate that these features are those recited in claim 1.

Claim 16 is alleged to be unclear for reciting subjective terms (“appropriate”, “suitable”). These terms are removed from claim 16 as currently amended. Also, claim 16 now specifies that the chemical substrate is a substrate for the enzyme linked to the third antibody (“required” is removed).

Claims 19 and 20 are alleged to be unclear for reciting a ready-to-use solid support of claim 1. Independent claim 20 is currently amended to recite a product-by-process; claim 19 now refers to this product as the ready-to-use solid support.

Other amendments are made for purposes of clarity and formality, and to correct typographical errors. Applicants respectfully submit that this rejection is overcome by entering the above amendments.

**Claim Rejections – 35 USC § 103(a)**

Four different rejections under 35 U.S.C. § 103(a) are made in the Office Action.

**Claims 1, 2, 4, 5, 7-11, 16, 19 and 20**

In the first rejection, claims 1, 2, 4, 5, 7-11, 16, 19 and 20 are alleged to be obvious over Rech-Weichselbraun et al. (US Appl. Publ. 2004/0171087) in view of Gatto-Menking et al. (US Appl. Publ. 2003/0108973). The Examiner further refers to Sawyer et al. (US Patent No. 5,602,041; c. 1, ll. 13-42), which discloses the stabilizing function of blocking agents.

Claim 1 as currently amended recites that the stabilizer is incubated on the solid support for about 12-14 hours at about 4 °C. In addition, claim 1 now recites that lyophilization of the support, to which multiple components (antibodies and stabilizer) have been applied, is performed for about 15 minutes. In contrast, Rech-Weichselbraun teaches blocking of antibody-adsorbed plates at room temperature for 2 hours (e.g., para. 0056), which is substantially warmer and of shorter duration than the recited conditions. Rech-Weichselbraun also teaches lyophilization for 20 hours (e.g., para. 0071), which is substantially longer than the 15-minute period recited in claim 1. Further, Rech-Weichselbraun describes use of biotin-streptavidin linked antibodies (e.g., Example 2). Gatto-Menking discloses compatible conditions: blocking at room temperature for 30 minutes (e.g., para. 0196), and lyophilization for at least 960 minutes (e.g. para. 0122). Therefore, Rech-Weichselbraun and Gatto-Menking do not teach or suggest all the limitations of the pending claims. Not only does Gatto-Menking teach different conditions, but this reference also teaches away from the 4 °C blocking condition of the claimed invention:

After incubation, goat serum was added to respective tubes in the volumes indicated in Table 2. The Dynabead-IgG complex was incubated for 30 minutes at ART [ambient room temperature] with gentle rocking on the rotator. The 30-minute incubation period was selected arbitrarily and was not based on any previous experience with this particular blocking format; however, if the block proved to be inefficient, future efforts would utilize longer blocking periods and/or blocking at 37° C.

p. 9, c. 2, ll. 34-42 (emphasis added). Instead of suggesting a temperature cooler than room temperature as an alternative blocking condition, Gatto-Menking suggests a warmer temperature. In addition to these differences, Applicants respectfully submit that the claimed invention provides features preferable to those of the ELISA system described by Rech-Weichselbraun; please refer to the specification (p. 2, ll. 7-20). Applicants respectfully submit that this particular obviousness rejection is overcome.

#### Claims 3, 12 and 13

In the second rejection, claims 3, 12 and 13 are alleged to be obvious over Rech-Weichselbraun and Gatto-Menking as applied in the first rejection in further view of Rogan et al. (1999, *Food Control* 10:407-414). Rogan is cited as teaching 5-enolpyruvylshikimate-3-phosphate synthase as the protein to be detected by ELISA.

As discussed in the above remarks, Rech-Weichselbraun and Gatto-Menking do not teach or suggest all the limitations of the pending claims. Rogan does not cure this deficiency. Therefore, Applicants respectfully submit that this particular obviousness rejection is overcome.

#### Claim 6

In the third rejection, claim 6 is alleged to be obvious over Rech-Weichselbraun and Gatto-Menking as applied in the first rejection in further view of Vogt et al. (1987, *J. Immunol. Meth.* 101:43-50). Vogt is cited as teaching fish gelatin as a blocking/stabilizing agent.

As discussed in the above remarks, Rech-Weichselbraun and Gatto-Menking do not teach or suggest all the limitations of the pending claims. Vogt does not cure this deficiency. Therefore, Applicants respectfully submit that this particular obviousness rejection is overcome.

Claims 14, 15 and 18

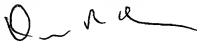
In the fourth rejection, claims 14, 15 and 18 are alleged to be obvious over Rech-Weichselbraun, Gatto-Menking and Rogan as applied against claims 1-5, 7-13, 16, 19 and 20 (first and second rejections) in further view of Padgett et al. (1995, *Crop Sci.* 35:1451-1461). Padgett is cited as teaching that alkaline phosphatase and antibodies obtained from the class Mammalia can be used in ELISA.

As discussed in the above remarks, Rech-Weichselbraun, Gatto-Menking and Rogan do not teach or suggest all the limitations of the pending claims. Padgett does not cure this deficiency. Therefore, Applicants respectfully submit that this particular obviousness rejection is overcome.

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No fee is believed to be due for filing this response. However, the Commissioner is hereby authorized to charge any underpayment of fees to Howrey LLP Deposit Account No. 08-3038/04725.0002.PCUS00.

Respectfully submitted,



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